

Serial No. 10/714,767

Dkt.: P0011092.00

Filing Date: November 17, 2003

Title: IMPLANTABLE HEART VALVE PROSTHETIC DEVICES HAVING INTRINSICALLY
CONDUCTIVE POLYMERS

Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks presented herein, is respectfully requested.

Claims 1, 7 and 20 are amended, and claims 4, 7-19, 21, 23-25, 27-41 and 44 are withdrawn from consideration. The pending claims are claims 1-20, 22, 26 and 44.

Support for the amendments to claims 1 and 20 is found in the specification, for example, at page 7, lines 3-7. No new matter has been added by way of this amendment.

It is respectfully submitted that upon allowance of generic claims 1 and/or 20, Applicants are entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR §1.141. M.P.E.P. § 809.02. Therefore, the Examiner is respectfully requested to reconsider the withdrawal of claims 4, 7-19 and 44.

Withdrawal of final rejection as being premature requested

Applicants' note that the "Office Action Summary" page indicates that the Office Action mailed December 27, 2007 (the "Office Action") in the above-identified application has been made FINAL. It is respectfully submitted that final rejection in this case is premature. In particular, it is respectfully submitted that the rejections of claims 1-2, 5-6, 20, 22 and 26 under 35 U.S.C. § 102(b) as being anticipated by Ogle *et al.* (U.S. Patent No. 6,190,407) and the rejection of claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Ogle *et al.* in view of Carpentier *et al.* (U.S. Patent No. 4,055,861) are new grounds for rejection that are neither necessitated by Applicants' amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. §1.97(c). M.P.E.P. § 706.07(a). Therefore, it is submitted that the final rejection is not proper, and Applicants' request reconsideration and withdrawal of the finality of the rejection of the Office Action.

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The 35 U.S.C. § 102(b) Rejection

The Examiner rejected claims 1-2, 5-6, 20, 22 and 26 under 35 U.S.C. § 102(b) as being anticipated by Ogle *et al.* (U.S. Patent No. 6,190,407). This rejection is respectfully traversed.

As amended, the claims are directed to an implantable heart valve sewing prosthesis comprising a ring shaped body having a blood contacting external surface including an intrinsically conductive polymer having a resistivity of less than about 2000 ohms per square, wherein the intrinsically conductive polymer does not require a metallic filler or coating; and to an annuloplasty prosthesis for implanting in a heart valve annulus in a patient, the annuloplasty prosthesis comprising a ring shaped body comprising a blood contacting external surface comprising an intrinsically conductive polymer, wherein the intrinsically conductive polymer does not require a metallic filler or coating.

The standard for anticipation is one of strict identity, and to anticipate a claim for a patent a single prior art source must contain all its elements. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ2d 90 (Fed. Cir. 1986); In re Dillon, 16 USPQ2d 1987 (Fed. Cir. 1990). Furthermore, there must be no difference between the claimed invention and the disclosure, as view by a person of ordinary skill in the art. Scripps Clinic & Res. Found. v. Genentech, Inc., 18 USPQ2d 101 (Fed. Cir. 1991).

Ogle *et al.* disclose a medical article having an tissue-contacting surface coated, at least in part, with an antimicrobial metal in order to reduce the “very serious and even life threatening” risk of infection following implantation, such as prosthetic valve endocarditis (PVE) (abstract; column 1, lines 33-34; column 2, lines 1-19; column 4, lines 29-44; line 66-column 5, line 5). For example, Ogle *et al.* disclose prosthesis, including as the Examiner notes sewing rings and annuloplasty rings, coated entirely with an antimicrobial metal (column 4, lines 29-36). Ogle *et al.* further disclose partially coating prosthetic articles with the antimicrobial metal, *e.g.*, coating only the parts of the prosthesis that contact tissue (column 4, lines 40-42). However, Ogle *et al.* do not disclose Applicants’ claimed invention.

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Therefore, withdrawal of the 35 U.S.C. §102(b) rejection is therefore proper and respectfully requested.

The 35 U.S.C. § 103(a) rejection of the claims

The Examiner rejected claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Ogle et al. in view of Carpentier et al. (U.S. Patent No. 4,055,861). In particular, the Examiner asserts it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical articles of Ogle *et al.* with the semi-annular ring of Carpentier *et al.* This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the cited references themselves or in the knowledge generally available to an art worker, to modify the reference or to combine reference teachings so as to arrive at the claimed invention. Second, the art must provide a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. M.P.E.P. § 2143. The teaching or suggestion to arrive at the claimed invention and the reasonable expectation of success must be found in the prior art, not in Applicant's disclosure. M.P.E.P. § 2143 citing with favor *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

As discussed above, Ogle *et al.* do not disclose or suggest all the limitations of Applicants' claims.

Carpentier *et al.* do not remedy the deficiencies of Ogle *et al.* Carpentier *et al.* disclose a support for a natural human heart valve that consists of an annular or part annular semi-rigid frame, which frame can be covered by a textile sheath (abstract). Carpentier *et al.* disclose that the device can be made of polyesters such as poly(ethylene terephthalate) or poly (glycol terephthalate), polyamides such as nylon 6--6, nylon 11 or nylon 12, polyolefins, polypropylene, fluorinated polymers such as polytetrafluoroethylene, or polyvinyl chloride (column 3, lines 39-45). Carpentier *et al.* further disclose that the textile sheath can be (i) produced from a woven fabric, *e.g.*, a

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napped fabric or a cut velour; (ii) a knitted or braided sleeve; or (iii) made of a non-woven fabric (column 3, lines 15-18). However, there is nothing in Carpentier *et al.* that teaches or suggests an implantable heart valve sewing prosthesis comprising a ring shaped body having an external surface including an intrinsically conductive polymer having a resistivity of less than about 2000 ohms per square, wherein the intrinsically conductive polymer does not require a metallic filler or coating; or an annuloplasty prosthesis for implanting in a heart valve annulus in a patient, the annuloplasty prosthesis comprising a ring shaped body comprising an intrinsically conductive polymer, wherein the intrinsically conductive polymer does not require a metallic filler or coating. Therefore, the pending claims are not obvious in view of Carpentier *et al.*

It is respectfully submitted that *prima facie* obviousness has not been established. As discussed above, neither Ogle *et al.* nor Carpentier *et al.*, either alone or in combination, disclose or suggest Applicants' claimed invention. Moreover, at page 3 of the Office Action, the Examiner concedes that Ogle *et al.* do not disclose an annular gap that is not closed upon itself. Given that Ogle *et al.* disclose coating all or some of the tissue-contacting surfaces of a medical article with an antimicrobial metal to prevent serious side effects following implantation, it is respectfully submitted that the art worker would not be motivated to modify Ogle *et al.* as the Examiner asserts, and that the art worker would have no reasonable expectation that a implantable prosthesis having an intrinsically conductive polymer that does not require a metallic filler or coating would be successful. Furthermore, Applicants' submit that Ogle *et al.* actually *teach away* from the claimed invention.

Therefore, one of ordinary skill in the art would not be motivated to combine the teachings of the cited art so as to arrive at the presently claimed invention. Hence, the claims of the present invention are distinct from the cited art. Withdrawal of the 35 U.S.C. §103(a) rejection of the claims is therefore proper and respectfully requested.

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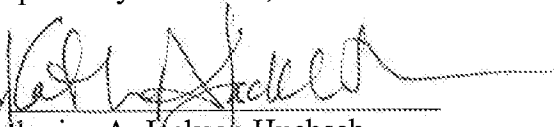
Conclusion

Applicants' respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney (763-505-8423) to facilitate prosecution of this application.

Please charge any required fees or credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

Date: March 27, 2008

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